Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
LISA HYDE and MARK HYDE, a married couple, Plaintiffs, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFFS' TRIAL BRIEF** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

I. KEY FACTS

The Defendants in this case are C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. ("BPV"). BPV is the wholly-owned subsidiary of C. R. Bard, Inc., the parent company. Throughout this case, the jury instructions and the verdict form, C.R. Bard, Inc. and BPV will be referred to collectively as "Bard" or "Defendants."

The product the subject of this lawsuit is a retrievable Bard IVC Filter[1] ("Filter") designed, manufactured, marketed and sold by Bard; The Filter is conical in shape and consists of a main shaft to which twelve struts (six "arms" and six "legs") are attached; The Filter is constructed of a nickel-titanium alloy called Nitinol; The Filter is a medical device that is implanted in the inferior vena cava ("IVC"), the largest vein in the human body; The United States Food and Drug Administration ("FDA") cleared the Filter for commercial availability through the 510(k) process outlined in the Food, Drug and Cosmetic Act ("FCDA"); The G2X® IVC Filter was cleared for commercial availability in the United States for use in patients as a permanent filter with the option for retrieval on October 31, 2008; The Eclipse IVC Filter was cleared for commercial availability in the United States for use in patients as a permanent filter with the option for retrieval on November 23, 2009.

Plaintiff Lisa Hyde was under the care of Dr. Vinodkumar Shah, M.D. who referred Mrs. Hyde to Dr. David Henry, an interventional radiologist, for_consultation regarding possible IVC filter. On February 25, 2011, Dr. David Henry implanted the Filter in Mrs. Hyde's inferior vena cava. On May 6, 2014, Mrs. Hyde underwent a CT scan revealing her IVC Filter had fractured and perforated her IVC with the fractured strut having migrated to her right ventricle. On August 26, 2014, Dr. William Kuo removed the Filter and fractured strut through a complex percutaneous procedure.

II. PLAINTIFFS' CAUSES OF ACTION

Mr. and Mrs. Hyde assert five claims against Bard: (1) Strict Product Liability Based on Design Defect; (2) Negligent Design; (3) Negligence Per Se; (4) Loss of Consortium and (5) Punitive Damages.

A. Design Defect - Whether the Filter Was Defective In Its Design.

[1] Plaintiffs and Defendants dispute the specific identity of the filter. Plaintiffs contend the filter implanted in Mrs. Hyde was a G2X Filter, Defendants contend the filter was an Eclipse.

Mrs. Hyde contends that the implanted IVC filter she received was a G2X filter. Mrs. Hyde will present evidence that the Filter she received was defective in design, where the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, the omission of which rendered the Filter unsafe. Mrs. Hyde further contends that the Filter implanted in her IVC caudally migrated and tilted after it was properly implanted; that the Filter struts subsequently perforated through her vena cava and then penetrated into her retroperitoneum, and that 1 of the fractured struts of the Filter fractured, and embolized/migrated to the right ventricle of her heart requiring interventional surgery.

Plaintiffs will present evidence that as the ultimate consumer, Plaintiff did not expect this product to migrate and fracture more than a safer alternative design. The evidence will show it was feasible and economical to make the product much safer with caudal anchors and penetration limiters and that safer filters were on the market. Plaintiffs' expert Dr. Robert McMeeking, among others, will testify about the defective design characteristics and the feasibility of an alternative design.

B. <u>Negligent Design – Whether Bard was negligent in the design of the Filter</u>

Mrs. Hyde contends that Bard failed to use that degree of care which is used by ordinary careful persons under the same or similar circumstances in the design and/or testing of the Filter that was implanted in her. Mrs. Hyde further contends that the Filter implanted in her migrated and tilted after it was properly implanted in her vena cava; that the Filter struts perforated through her vena cava and then penetrated into her retroperitoneum; that 1 of the struts of the Filter fractured and embolized/migrated to the right ventricle of the heart requiring interventional surgery; and that Defendants' negligence/lack of ordinary care in the design of its Filter, and negligence/lack of ordinary care in testing its Filter caused her injuries and damages. Defendants' lack of proper testing of the filter is evidence of their failure to act reasonably and use the proper degree of care, as well as their breach of the duty of care.

C. Negligence *Per Se*: Whether Defendants Violated A Safety Statute Which Was Designed To Prevent Injuries To Patients Like Plaintiff Lisa Hyde

Mrs. Hyde contends that Bard's negligence per se caused or contributed to cause her injuries and damages. These statutes are cited merely to demonstrate the standard of care applicable. Plaintiff is not seeking to enforce these statutes on behalf of the FDA. Instead, Plaintiff cites to these statutes as evidence of the standard of care required under the law for the purpose of protecting patients like Ms. Hyde: Mrs. Hyde contends that Bard's actions violated the following regulations and statutes to her: 21 U.S.C. § 331; 21 U.S.C. §352; 21 C.F.R. 803; 21 C.F.R. 806; 21 C.F.R. 820.250; 21 U.S.321; 21 C.F.R. 820.100; 21 C.F.R. 820.198; 21 C.F.R. 803.

Plaintiffs will have expert testimony on these regulations as standards for Bard that applied to the Plaintiffs. These regulations include maintaining and reporting adverse events for serious injury or death and determining causes for those injuries or deaths including the defects in their design. This also required an evaluation of whether the product was as safe for its intended use. If the product does not meet these standards it is considered adulterated or misbranded and the regulations determine what corrective action is necessary including monitoring, withdrawal or safety notifications.

§ 803.1 Scope. (a) This part establishes requirements for medical device reporting. Under this part, device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed and must establish and maintain adverse event files. Manufacturers are also required to report certain device malfunctions and submit an annual report to FDA certifying that the correct number of medical device reports were filed during the previous 12-month period or, alternatively, that no reports were required during that same time period. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(d) Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) User error

21 C.F.R. 806

(a) This part implements the provisions of section 519(g) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device

21 C.F.R. 820.250

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

21 U.S.C. §321

(h) The term ‘‘device’’ (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (2) intended for the cure, mitigation, treatment, or prevention of disease, in man or other animals

21 C.F.R. 820.100

Sec. 820.100 Corrective and preventive action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

21 C.F.R. 820.198

Sec. 820.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

(1) All complaints are processed in a uniform and timely manner;

(2) Oral complaints are documented upon receipt; and

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor.

21 U.S.C. § 331

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded

21 U.S.C. §352.

A drug or device shall be deemed to be misbranded—

(a) FALSE OR MISLEADING LABEL

(1) If its labeling is false or misleading in any particular

D. Loss of Consortium

Plaintiffs Contention: Mr. Hyde has brought a loss of consortium action based upon the interference with their marital relationship.

E. Punitive Damages

Plaintiffs contend that Bard put profits before the safety of consumers like Mrs. Hyde and intentionally disregarded her safety by allowing a filter to be sold and implanted into her body with the knowledge that it would tilt, migrate and fracture more than other filters. Bard was acutely aware these migrations and fractures would result in serious injury. Bard also knew a safer alternative design already existed but would not be as profitable. In spite of this knowledge, Bard made an intentional decision to conceal this information while also continuing to market and sell the defective filter.

III. LAW

A. While Wisconsin Adopted A New Statutory Scheme In 2011, Common Law Rulings Not Inconsistent With This Scheme Are Still Good Law

Wisconsin's product liability law is a statutory scheme, enacted in 2011 which is not retroactive. *Forsythe v. Indian River Transp. Co.*, 822 N.W.2d 737, FN. 5 (Wis. Ct. App. 2012) (Noting that the act does not apply to cases filed prior to the 2001 enactment). Despite the enactment, common law is not superseded by the 2011 statutory scheme. As long as, pre-2011 common law rulings are not inconsistent with the statute, they stand. Wisconsin's 2011 codification of its product liability law generally "does not supersede the common law." *Janusz v. Symmetry Med. Inc*., 256 F. Supp. 3d 995, 1000 (E.D. Wis. 2017). Courts recognize this additive nature of pre-2011 common law and post-2001 statutory enactment. *Williams v. Boston Sci. Corp*., 2016 WL 1448860, at *4 (S.D.W. Va. 2016) (stating "because section 895.047 does not indicate whether it replaces the common law or merely supplements it, I will interpret it in addition to [common law].").

B. Bard Is Liable Under Both Strict Liability And Negligence For Its Defectively Designed Filter

1. Strict Liability – Design Defect Standard

Strict liability design defect claims are governed by Wis. Stat. 895.047 (2011):

> "In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:
> (a)…A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe…
>
> (b)That the defective condition rendered the product unreasonably dangerous to persons or property.

> (c) That the defective condition existed at the time the product left the control of the manufacturer.
>
> (d) That the product reached the user or consumer without substantial change in the condition in which it was sold.
>
> (e) That the defective condition was a cause of the claimant's damages."

"Unlike negligence, where the focus is upon the defendant's conduct, in strict liability the focus 'is on the dangerousness of the product regardless of the defendant's conduct.' Thus, a defendant may be blameless but strictly liable." *Janusz*, 256 F. Supp. 3d at 1001(citing *Flaminio v. Honda Motor Co.*, 733 F.2d 463, 469 (7th Cir. 1984)(applying Wisconsin law)). Yet even with this distinction, Plaintiffs are permitted to seek recovery from a manufacturer for the defective design of a product under a strict liability theory and/or a negligence theory. *Morden v. Cont'l AG*, 611 N.W.2d 659, 673 (Wis. 2000)(citing *Sharp v. Case Corp*., 595 N.W.2d 380, 382 (Wis. 1999).

2. Negligent Design and the Reasonable Alternative Design

In addition to her strict liability claim, plaintiff also asserts a negligence claim under Wisconsin common law. To succeed "on a negligent design defect claim, plaintiffs must prove: (1) the existence of a duty of care on the part of the defendant, (2) a breach of that duty of care, (3) a causal connection between the defendant's breach of the duty of care and the plaintiff's injury, and (4) actual loss or damage resulting from the [breach]." *Kilty v. Weyerhaeuser Co.*, 2018 WL 2464470, at *3-4 (W.D. Wis. 2018); *Rockweit v. Senecal*, 541 N.W.2d 742, 747 (Wis. 1995).

"As the Seventh Circuit has recognized, there is significant overlap between these two claims." *Kilty*, 2018 WL 2464470, at *3–4(citing *Krien v. Harsco Corp.*, 745 F.3d 313, 317 (7th Cir. 2014)(stating claim of "strict products liability is much like a negligence claim because it requires proof either that the product was unreasonably dangerous or, what amounts to the same thing, that it was defective.")(discussing

Wisconsin law)). Plaintiff is not required to make the same showing with respect to negligent design and strict liability design defect. *Below v. Yokohama Tire Corp*., 2017 WL 679153, at *3 (W.D. Wis. 2017). That is because the reasonableness of a product's design turns essentially on whether the manufacturer could have developed a less dangerous design. *Nationwide Agribusiness ins. Co. v. Meller Poultry Equip*., Inc. 2015 WL 998331, at *3 (E.D. Wis. 2015). What a manufacturer could have feasibly done at the time of the design or manufacture is relevant to the jury's determination of negligence. *Morden*, 611 N.W.2d at 658 (Wis. 2000). Manufacturers are held to the "reasonable person" standard of customary methods of manufacture in a similar industry and the jury can determine whether the manufacturer reasonably and economically could have chosen an alternative course of conduct. *Id*. (internal quotation marks and citation omitted).

3. The Risk/Benefit and Consumer Expectation Test

Prior to the 2011 PL statute, Wisconsin utilized the consumer expectation test (as opposed to the risk/benefit analysis). *See*, *In re Zimmer Nexgen Knee Implant Products Liab. Litig.*, 218 F. Supp. 3d 700, 723 (N.D. Ill. 2016), aff'd sub nom. *In re Zimmer, NexGen Knee Implant Products Liab. Litig.*, 884 F.3d 746 (7th Cir. 2018)(citing *Green v. Smith & Nephew AHP, Inc*., 629 N.W.2d 727, 739 (Wis. 2001)) (defining the test as, "if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer…"). Since the enactment of the 2011 product liability statute, the consumer expectation test has not been rejected by Wisconsin courts, and the Seventh Circuit, when interpreting Wisconsin law, agreed that a consumer's expectation is at least one factor to consider. *In re Zimmer*, 218 F. Supp. 3d at 723. In accordance with the *Janusz* decision discussed *supra*, any case that is not inconsistent with statutory law remains authoritative.

In passing the 2011 product liability stature, the Wisconsin legislature adopted the Restatement (Third) of Torts language in the statute. However, it is important to note that the legislature did not incorporate any of the comments to the Restatement (Third) in the language of the statute. Nor is there any Wisconsin case law that expressly adopts the comments. Any suggestion by Defendants that this Court should be a pioneer in adopting these comments (and thereby changing Wisconsin tort law) is inappropriate. Even assuming *arguendo* that this Court does apply the comments to the Restatement (Third), while the consumer expectation test was not codified in the 2011 Wisconsin product liability statute, the comments to the Restatement indicate that the test may still be considered:

> "The Restatement (Third) of Torts indicates that the consumer contemplation test may remain relevant even in some design defect cases. Comment g to sec. 2 of the Restatement (Third) suggests that "although consumer expectations do not constitute an independent standard for judging the defectiveness of product designs, they may substantially influence or even be ultimately determinative on risk-utility balancing in judging whether the omission of a proposed alternative design renders the product not reasonably safe".

4. Causation

Whether a plaintiff pursues a strict liability or negligence theory, to prevail on a products liability claim, a plaintiff must prove that the alleged defect was a cause of the injury. *Robertson v. Cleaver-Brooks, Inc.*, 905 N.W.2d 843, at *4 (Wis. Ct. App. 2017), *review granted*, 2018 WI 20, ¶ 12, 380 Wis. 2d 105 (addressing causation) (citing *Morden v. Continental AG*, 611 N.W.2d 659, 676 (Wis. 2000) (negligence), and *Zielinski v. A.P. Green Indus., Inc.*, 661 N.W.2d 491, 597 (Wis. Ct. App. 2003) (strict products liability)).

5. Bard is not entitled to a rebuttable presumption under Wis. Stat. 895.047(3)(b)

Under Wisconsin Statute 895.047(3)(b) Bard may claim it is entitled to a rebuttable presumption. The statute reads:

> (b) Evidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective.

However, this Court's Order on Defendants' Motion For Summary Judgment precludes this defense stating: "Because the 510(k) clearance process focuses on equivalence, not safety, the presumption of non-defectiveness afforded by 895.047(3)(b) is not applicable". (Doc. 12007, at 12)

Defendant also now cites *Kilty*, 16-CV-515-WMC, 2018 WL 2464470, at *3–4, to claim that a rebuttable presumption is applicable. Indeed, the *Kilty* Court states, "Where a governmental agency issues certain regulations, requires compliance with those regulations, and then issues and reissues a certification based on a demonstration that those requirements are met, the presumption applies. *Id.*

In the present case, there is no evidence that the FDA issued Bard a safety certification that these regulation requirements were being met. Therefore, the presumption does not apply.

6. The "Inherent Characteristic" Defense Also Does Not Apply.

Wis. Stat. § 895.047(3)(d) provides the following defense in a product liability action:

> (d) The court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Previously in motions *in limine*, Defendants cited to one Wisconsin case to argue that a reasonable alternative design must not "make the product something else." *See Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 743 N.W.2d 159, 162 (2007). The retrieval option of the G2/G2X /Eclipse filter is not an ingredient, like in *Godoy*, that makes the product "something else." This "ingredient defense" when made

in a similar manner failed in other courts interpreting § 895.047(3)(d). *Williams v. Boston Sci. Corp*., 2016 WL 1448860, at *4 (S.D.W. Va. 2016).

Filter fracture can be prevented or limited. These devices can be considered as much a permanent device as an optional device; in fact, its similarity to its permanent predecessors is the very reason Bard was able to use the 510(k) application process instead of the more rigorous PMA process to seek clearance of its products. If the device can be used both permanently and temporarily, it cannot be logically argued that one or the other is an ingredient that "makes the product something else."

Additionally, filter fracture and other failure modes such as migration, tilt and penetration are not an inherent characteristics which would be apparent or known to a consumer as compared to the sharpness of a knife which would be known to the ordinary consumer. Filter failure modes can be prevented or limited as Plaintiffs' experts will opine.

C. Bard is Negligent *Per Se* for Violations of Federal Regulations

Under Wisconsin law, "[f]or the violation of a safety statute to constitute negligence per se, a plaintiff must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a basis for the imposition for civil liability." *Tatur v. Solsrud*, 498 N.W.2d 232, 235 (Wis. 1993); Wis. JI-Civil 1009.

The Wisconsin Court of Appeals has held that, "[i]n Wisconsin, violations of FDA regulations may constitute negligence per se." since they are safety statutes. *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. Ct. App. 2004) (citing *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981), *amended*, 532 F. Supp. 211 (E.D. Wis. 1981) *See* https://www.fda.gov/aboutfda/transparency/basics/ucm214416.htm ("The FDCA was the "first comprehensive federal *consumer protection law*…") (emphasis added).

The Wisconsin Supreme Court has also explained:

> [A] safety statute merely establishes a minimum standard of care and the conduct, even though sanctioned or in conformity with the statute, is not thereby necessarily relieved of conforming to the common-law requirements of ordinary care. In any event the establishment of a statutory definition of negligence per se does not thereby result in a preemption of the entire negligence question. There remains the question of possible common-law negligence. (*Hoffmann v. Wisconsin Elec. Power Co.*, 664 N.W.2d 55, 62 (Wis. 2003)(citations omitted).

Moreover, a "statute does not change the common law unless the legislative purpose to do so is clearly expressed in the language of the statute." *Id*.; *see also Fuchsgruber v. Custom Accessories, Inc.*, 628 N.W.2d 833, 841(Wis. 2001) (stating to "accomplish a change in the common law, the language of the statute must be clear, unambiguous, and peremptory.") (citations omitted).

D. Plaintiff's Claims Are Not Impliedly Preempted Under *Buckman*

Bard cites *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) to claim that Plaintiffs' negligence *per se* claims are preempted. This is a red herring, and the defense has no place in this case. *Buckman*, however, is completely inapposite. In *Buckman*, patients claimed they suffered injuries from implantation of orthopedic bone screws into their spines. *Id*. at 343. After settling claims against the device manufacturer, the plaintiffs proceeded on a suit solely against a regulatory consultant they alleged made fraudulent representations to the FDA in the course of the FDA approval process. *Id.* This claim has come to be known as a "fraud-on-the-FDA" claim.

As described by the Court, the critical failure of the *Buckman* "fraud-on-the-FDA" claim was that the claim was not based on "traditional state tort law principles of the duty of care owed by" the defendant to the plaintiff, *Id.* at 352, but instead rested entirely on alleged duties arising from "the relationship between a federal agency and the entity it regulates," *Id.* at 347. Thus, the sole interest that the claim sought to advance was to "punish and deter fraud against the [FDA]." *Id*. at 348. That objective, the Court

stressed, was one in which the states had no independent interest. *Id.* Thus, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to policy fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

Here, by contrast, the essence of Ms. Hyde's claims is not that Bard breached duties to the FDA, but that it breached duties *to her*. Ms. Hyde is not suing to enforce the federal prohibition against misbranding or adulteration, but instead under longstanding state-law causes of action, which pre-existed any federal regulation of medical devices.

While these causes of action address conduct that also violates federal law, they do not constitute an attempt to privately enforce those federal requirements. These references are present solely to demonstrate the standard of care applicable to Bard. *Buckman* is distinguishable because the present claims are based upon Wisconsin common law negligence, not on the FDCA regulations. To support their claims of negligence *per se*, Plaintiffs will establish that Defendant negligently failed to design IVC filters in a manner that complied with the previously cited regulations. Plaintiffs are not attempting to enforce federal regulations; rather they are relying on them to establish the standard of care in the negligence claim.

Nor are plaintiff's claims impliedly preempted. This is so because none of them arise solely from a violation of federal law. \Rather, each claim arises from an independent, well-recognized duty owed under state law. *Id.* at 353(distinguishing between claims arising "from the manufacturer's alleged failure to use reasonable care" and claims arising "solely" from a violation of a federal requirement); *Bausch v. Stryker Corp.*, 630 F.3d 546, 558(7th Cir. 2010)(holding that claims which allege a "breach of a well-recognized duty owed to [plaintiff] under state law" are not impliedly preempted); *see Garross v Medtronic, Inc.* 77 F.Supp. 3d 809, 814 (E.D. Wis. 2015)*; see also Marvin v Zydus Pharmaceuticals. (USA), Inc.* 203 F. Supp. 3d 985, 988-992 (W.D. Wis. 2016) (also denying the applicability of implied preemption to negligence per se claims)

E. Bard's Conduct Merits An Award of Punitive Damages

Punitive damages under Wisconsin law are governed by Wis. Stat. § 895.043.

Pursuant to section 3, a "plaintiff may receive punitive damages if evidence is submitted showing that the defendant acted maliciously toward the plaintiff or in an intentional disregard for the rights of the plaintiff." Wis. Stat. § 895.043(3). "[T]he purpose of punitive damages is to punish the wrongdoer, and to deter the wrongdoer and others from similar conduct, rather than to compensate the plaintiff for any loss…[O]nly when an award can be fairly categorized as 'grossly excessive,' in relation to the [S]tate's interests in punishment and deterrence, does it enter the zone of arbitrariness that violates due process." *J.K. v. Peters*, 808 N.W.2d 141, 154 (Wis. Ct. App. 2011).

Punitive damages in Wisconsin "may not exceed twice the amount of any compensatory damages recovered by the plaintiff or $200,000, whichever is greater." Wis. Stat. § 895.043(6).

1. The "Intentional Disregard" Standard

"In order to meet the 'intentional disregard' standard, the defendant's conduct must be (1) deliberate, (2) in actual disregard of the rights of another, and (3) 'sufficiently aggravated to warrant punishment by punitive damages.' *Centrifugal Acquisition Corp. v. Moon*, 849 F. Supp. 2d 814, 839 (E.D. Wis. 2012) (citing *Berner Cheese Corp. v. Krug*, 752 N.W.2d 800, 814 (Wis. 2008)). A defendant's conduct giving rise to punitive damages need not be directed at the plaintiff seeking punitive damages. This burden does not require a plaintiff to show that defendant intended to cause harm or injury to the plaintiff. *Wosinski v. Advance Cast Stone Co.*, 901 N.W.2d 797, 820-21 (Wis. Ct. App. 2017) (citing *Strenke v. Hogner*, 694 N.W.2d 296 (Wis. 2005)).

2. Factors Influencing the Amount of Punitive Damages Awarded

"If the finder of fact concludes punitive damages are available and decides to award them, it then determines the amount of punitive damages by considering factors such as the grievousness of the defendant's acts, the degree of malice involved, the potential damage which might have been done by such acts as well as the actual damage, and the defendant's ability to pay." *Centrifugal*, 849 F. Supp. 2d at 839 (quoting *Boelter*

v. Tschantz, 779 N.W.2d 467, 474 (Wis. Ct. App. 2009)). A plaintiff who establishes a prima facie case for punitive damages may introduce evidence of the defendant's wealth, and the "judge shall submit to the jury a special verdict as to punitive damages…" Wis. Stat. § 895.043(4). Other factors which may be considered include:

1. the seriousness of the hazard to the public;
2. the profitability of the misconduct;
3. the attitude and conduct on discovery of the misconduct;
4. the degree of the manufacturer's awareness of the hazard and of its excessiveness;
5. the employees involved in causing or concealing the misconduct;
6. the duration of both the improper behavior and its concealment;
7. the financial condition of the manufacturer and the probable effect on the manufacturer of a particular judgment; and
8. the total punishment the manufacturer will probably receive from other sources.

Wis. JI-Civil 1707.2.

3. Bard's Failure to take Post-Sale Remedial Actions isActionable Under Wisconsin Law As a Component of the Punitive Damages Analysis

Wisconsin law recognized a manufacturer's post-sale duty to remediate as far back as 1979. *See Kozlowski v. John E. Smith's Sons Co.*, 275 N.W.2d 915, 923-24 (Wis. 1979). While that case pre-dates the enactment of the 2011 product liability statute, Courts have cited the decision favorably since then. For example, in *Bushmaker v. A.W. Chesterton Co.*, 2013 WL 11079371 (W.D. Wis. 2013), the court examined a case where the plaintiff in an asbestos case argued "that once defendant learned that asbestos-containing products were hazardous, it had a duty to recall its products or to provide warnings about the danger." *Id.* at *6. The *Bushmaker* court cited to section 10 the

Restatement (Third) of Torts[2] and found "that in order for a duty to warn, post-sale, to exist, the plaintiff must have some evidence of the sort presented in *Sharp*, namely that it was both practically and economically feasible for the defendant to have provided warnings and that any warnings would have been effective in reaching the users of its products." *Id*. at *8.

The *Bushmaker* court also discussed the applicability of another pre-2011 case: *Sharp ex rel. Gordon v. Case Corp*., 595 N.W.2d 380, 390 (Wis. 1999) and summarized its relevance to the punitive damages claim as follows:

> In *Sharp*, the plaintiff's arms were amputated when a tractor's power take-off (PTO) shaft engaged without warning as he attempted to clear hay from a baler powered by the PTO….
>
> Notably, the case was submitted to the jury on the post-sale failure to warn theory even though there appears to have been no evidence that Case had developed a safety device in response to the problems reported about its tractor's PTO lever. On the other hand the defendant did not challenge the propriety of the special verdict question on appeal, so we don't know whether the viability of a post-sale failure to warn theory was ever in dispute. That said, the court did mention Case's failure to take "adequate remedial procedures such as product recalls or post-sale warnings," as evidence upon which a jury could make a finding of punitive damages. *Id*. at 23. If, as defendant argues here, a defendant cannot be liable at all for a post-sale failure to warn, then it would follow that it would be improper to consider evidence of such conduct in the punitive damages assessment. Accordingly, *Sharp* indicates that *Kozlowski* 's holding is limited to the failure-to-warn-of-safety-improvements scenario and that a manufacturer may in other instances have a post-sale duty to warn.

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[2] The Restatement (Third), then explains that a reasonable person would issue such a warning if:

(1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
(2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
(3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
(4) the risk of harm is sufficiently great to justify the burden of providing a warning.

Bushmaker, 2013 WL 11079371, at *7.

Bushmaker, 2013 WL 11079371, at *7.

Bard knew it was feasible to use caudal anchors and penetration limiters to make these products safer but intentionally refused do so at that time. The only rationale for this was profit. As a result Plaintiff received the defective device without any of this knowledge. Even after Plaintiff had this device implanted, Bard still could have prevented her injuries by notifying and warning her or her doctors of the increased risks of migration and fracture and the need to have the filter monitored and removed immediately. But again, Bard intentionally chose not to do so and led her doctors to believe it was as safe as other permanent filters such as the SNF. Instead, the predictable happened and Ms. Hyde's filter fractured and migrated into her heart. In short, Bard willfully and intentionally ignored her safety and caused the Plaintiffs' injuries justifying punitive damages.

RESPECTFULLY SUBMITTED this 28th day of August, 2018.

GALLAGHER & KENNEDY, P.A.

By: */s/ Mark S. O'Connor*

Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Marilyn B. Wass